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PATENT  
Attorney Docket No. 212583

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Nickoloff et al.

Art Unit: 1646

Application No. 09/944,849

Examiner: Claire Kaufman

Filed: August 31, 2001

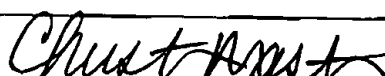
For: METHOD AND REAGENTS FOR  
EPITHELIAL BARRIER FORMATION  
AND TREATMENT OF MALIGNANT  
AND BENIGN SKIN DISORDERS BY  
MODULATING THE NOTCH  
PATHWAY

## RESPONSE TO OFFICE ACTION

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated May 22, 2003, please enter the following amendments and consider the following remarks.

CERTIFICATE OF MAILING OR TRANSMISSION UNDER 37 CFR 1.8			
I hereby certify that this Response to Office Action and all accompanying documents are, on the date indicated below, <input type="checkbox"/> being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop , Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or <input checked="" type="checkbox"/> being facsimile transmitted to the U.S. Patent and Trademark Office, Attention: Examiner Claire Kaufman, Art Unit 1646, Facsimile Number 703-308-4242.			
Name (Print/Type)	Christina Masters		
Signature		Date	June 23, 2003

In re Application of Nickoloff et al.  
Application No. 09/944,849

### Summary of Office Action

The Office Action sets forth a restriction requirement, identifying 15 groups of claims. The Office Action also calls for the election of a species of Notch agonist, Notch antagonist, and biopsy protein.

### Discussion of Restriction Requirement

In response to the restriction requirement, applicants hereby elect, with traverse, the Group II claims (claims 1-4 and 6-17) for further prosecution. However, for the following reasons, the requirement should be withdrawn and all claims examined concurrently.

MPEP § 803 requires two separate criteria to be met to support a proper requirement for restriction between groups of claims:

- (i) the inventions must be independent or distinct as claimed,
- AND
- (ii) there must be a serious burden on the Office if restriction is not required.

In the case at hand, the Office has failed to satisfy these criteria.

The sole basis the Office sites for requiring restriction is that the Groups are allegedly distinct. However, the alleged distinctiveness of the Groups cannot by itself support a restriction requirement. In this respect, the MPEP provides that "[I]f the search and examination of an entire application can be made without serious burden, the Office must examine it on the merits, even though it includes claims to distinct or independent inventions." (MPEP § 803, emphasis added) Even if the claims can be said to define separate inventions, the burden to search them must also be undue to support a requirement to restrict the claims (MPEP § 803). In this case, the Office has not asserted, let alone demonstrated, that it would encounter an undue burden in the absence of claim restriction. By failing to do so, the Office has not made out a prima facie case for the restriction requirement.

### Discussion of Election of Species

Applicant traverses the requirements to elect species because the election is not necessary for purposes of examining the elected Group. However, to comply with the requirement to elect species, applicant elects the following:

In re Application of Nickoloff et al.  
Application No. 09/944,849

**Notch Agonist:** a protein having a sequence of amino acids consisting essentially of SEQ ID NO:10. The claims that read on this species include claims 1-3, 6-19, 22-35, 40-43, 45-46, 49, 50, and 53.

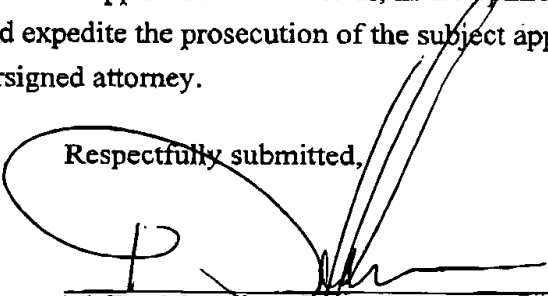
**Notch Antagonist:** gamma secretase inhibitor. The claims that read on this species include claims 43-47.

**Biopsy Protein:** Notch-4. The claims that read on this species include claim 50-53.

Conclusion

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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Date: June 23, 2003

**FAX RECEIVED**

**JUN 23 2003**

**GROUP 1600**

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U.S. PATENT APPLICATION No. 09/944,849

ATTORNEY DOCKET No. 212583

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**TO: CLAIRE M. KAUFMAN**  
EXAMINER  
ART UNIT: 1646  
UNITED STATES PATENT AND TRADEMARK OFFICE  
ALEXANDRIA, VA

TELEPHONE NUMBER: 703/305-5791  
FACSIMILE NUMBER: 703/308-4242

IN RE APPLN. OF: NICKOLOFF ET AL.  
PATENT APPLICATION No. 09/944,849  
FILED: AUGUST 31, 2001  
FOR: METHOD AND REAGENTS FOR EPITHELIAL BARRIER  
FORMATION AND TREATMENT OF MALIGNANT AND  
BENIGN SKIN DISORDERS BY MODULATING THE NOTCH  
PATHWAY

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OFFICIAL

In re Application of: Nickoloff et al.

Application No. 09/944,849

Filed: August 31, 2001

For: METHOD AND REAGENTS FOR EPITHELIAL BARRIER FORMATION AND TREATMENT OF  
MALIGNANT AND BENIGN SKIN DISORDERS BY MODULATION THE NOTCH PATHWAYMail Stop Non-fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is a response to an office action in the subject application.

☒ Applicants claim small entity status of this application under 37 CFR 1.27.☒ Petition for Extension of Time☐ Applicants petition for a one-month extension of time under 37 CFR 1.136, the fee for which is \$0.00 (enclosed).☒ Applicants believe that no petition for an extension of time is necessary. However, to the extent that such petition is deemed necessary, Applicants hereby petition for a sufficient extension of time to render the present submission timely. Please charge Deposit Account No. 12-1216 for the appropriate petition fee.☒ No additional claim fee is required.☐ Other:

The claim fee has been calculated as shown below:

					SMALL ENTITY		OTHER THAN A SMALL ENTITY	
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	EXTRA CLAIMS PRESENT	RATE	ADDIT. CLAIM FEE	RATE	ADDIT. CLAIM FEE
TOTAL	53	MINUS	53	=0	x 9=	\$	x 18=	\$
INDEPENDENT	9	MINUS	9	=0	x 42=	\$	x 84=	\$
<input type="checkbox"/>	FIRST PRESENTATION OF MULTIPLE CLAIM				+ 140=	\$	+ 280=	\$
					TOTAL	\$0.00	TOTAL	\$

☐ Please charge my Deposit Account No. 12-1216 in the amount of \$0.00. A duplicate copy of this sheet is attached.☐ A check in the amount of \$ is attached.☒ The Commissioner is hereby authorized to charge any deficiencies in the following fees associated with this communication or credit any overpayment to Deposit Account No. 12-1216. A duplicate copy of this sheet is attached.☒ Any filing fees under 37 CFR 1.16 for the presentation of extra claims.☒ Any patent application processing fees under 37 CFR 1.17.Respectfully submitted,  
LEYDIG, VOIT & MAYER, LTD.

By

M. Daniel Hefner, Reg. No. 41,826

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